DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8/17/11 have been fully considered but they are not persuasive. Applicant argues that the fact that the 3D models are projected onto a 2D image would cause a lack of precision in determining the implant insertion. However, the claim does not require a 3D display and only requires *calculating* a 3D geometry of the alterations. As discussed in par.52 of Sati, 3D models of the instrument and the implant are used to create the 2D projected images. Therefore, the system of Sati must first track and make calculations in 3D in order to project the 2D image. Applicant further argues that Sati calculates leg length in a 2D environment, namely the frontal plane, but pars. 64-79 of Sati also disclose calculating anteversion using 3D (par.67), as well as leg length, therefore 3D alterations are calculated. Finally, applicant argues that Sati simply tracks the reamer for position rather than tracking the rasp in 3D to obtain alterations for fitting of a 3D model of an implant, but pars.52 and 64-79 clearly disclose that the 3D position of the reamer is used to calculate and display real-time changes to implant insertion.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
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> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

> only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-5 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Sati et al. 2005/0203384 (hereafter referred to as Sati).

Re claim 1, Sati discloses a method of doing surgical treatment with a tracking system in computer-assisted surgery for guiding an operator in inserting a femoral implant of a hip joint implant in a femur as a function of a limb length and orientation of the femoral implant, comprising the steps of obtaining a frame of reference of the femur, the frame of reference being trackable in space (pars.37 and 50), obtaining a digital model of a femoral implant (pars.12, 27, and 38-40) and a digital model of a geometry of a tooling end of a rasp (pars.30, 33, 52, 63, and 64), calculating a desired implant insertion for the femoral implant with respect to the frame of reference of the femur, as a function of the limb length (pars.27, 39, 59, and 77), calculating 3D geometry of alterations being made to a femur with real-time tracking of the rasp altering the femur for receiving the femoral implant and with the digital model of the geometry of the tooling end of the rasp (pars.33, 52, 63, 64, and 79) and determining a current implant insertion with respect to the desired implant insertion, the current implant insertion being calculated as a function of the digital model of the femoral implant and the calculated 3D geometry of the alterations (pars.77-80).

Re claim 2, see pars. 64, 71, 72, and 80.

Re claim 3, see par. 77.

Re claim 4, see par. 84.

Re claim 5, see pars. 37 and 50.

Re claim 10, see pars. 33, 64, 72, and 84.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sati as applied to claim 5 above, and further in view of Carson 2002/0198451 (hereafter referred to as Carson).

Re claim 6, Sati discloses the invention substantially as claimed and as discussed above. Sati further discloses using the center of the femoral head as a frame of reference of the femur (par.93). However, Sati does not disclose the specific steps of determining the center of the femoral head including positioning a reference system trackable in space for position and orientation onto the femur, dislocating the femur from the pelvis, creating a digital model of a surface of the femoral head as a function of the reference system, and calculating the center of the femoral head as a function of the digital model of the surface of the femoral head.

Carson teaches a CAS method, in the same field of endeavor, wherein a probe is used to designate a number of points on the femoral head for the purpose of allowing the computer to calculate the geometrical center which corresponds to the geometry of points collected (par.66).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method taught by Carson of digitizing points on the femoral head in order to calculate the center of the femoral head in the method of Sati.

Re claim 8, while Sati in view of Carson does not specifically disclose using the acetabulum to calculate the center of the femoral head, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the same method of surface digitization taught by Carson but applied to the acetabulum since the acetabulum and femoral head share a center of rotation. Using the surface of the acetabulum as opposed to the surface of the femoral head is a matter of design choice because applicant's specification does not disclose that using the acetabulum solves any stated problem or is for any particular purpose. Moreover, it appears that the method would perform equally well using the acetabulum rather than femoral head.

6. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sati in view of Carson as applied to claims 6 and 8 above, and further in view of Chen et al. 2004/0087852 (hereafter referred to as Chen). Sati in view of Carson discloses the invention substantially as claimed and as discussed above, but does not specifically disclose establishing femoral sagittal, frontal, and transverse planes by registering a sagittal plane with respect to the reference system by digitizing the anatomical axis of the femur, a midpoint of the epicondyles and a midpoint of a tibia corresponding to the femur, the anatomical axis and the midpoint of the malleoli lying in the sagittal plane, registering a frontal plane with respect to the reference system, and registering a transverse plane with respect to the reference system.

Chen teaches a CAS method, in the same field of endeavor, wherein points on the anatomy are digitized and used to create frontal, sagittal, and transverse planes (pars.14, 64-67, 74, 76) for the purpose of defining a three-dimensional coordinate system available for use in a computer-assisted surgical system for ascertaining position and alignment of an object with respect to an anatomical structure (pars.17, 21-23).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the steps taught by Chen for establishing a coordinate system on an anatomic structure with the method of Sati in view of Carson in order to improve the accuracy of the positioning of the tools and instruments during the surgical procedure. Since Sati specifically discloses critical positions of the instruments and femoral implant with respect to the anatomic femur, including leg length, inclination (varus/valgus angle), and anteversion, it would have been obvious to specifically define the planes with respect to the anatomic femur using known bony landmarks in order to further aid in the correct positioning of the instruments and implant.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 10:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Tom Sweet, at (571) 272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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